

**Good Laboratory Practices**  
**CLIA Non-Waived Tests – Moderately Complex**  
**Provider Performed Microscopy Procedures (PPM)**

**Required**

- ❑ Obtain Federal CLIA (Clinical Laboratory Improvement Amendments – 1988) Certificate for Provider Performed Microscopy Procedures (PPM)

Application [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia)

- ❑ Perform any test categorized by FDA (Federal Drug Administration) as waived + any of 9 microscopic tests \*

List [www.accessdata.fda.gov/scripts/cdrh/cfdoc/cfCLIA/search.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdoc/cfCLIA/search.cfm)

- ❑ Follow manufacturer's instructions for waived tests
- ❑ Follow applicable CLIA microscopic test regulations (subparts A, C, J, K)

For compliance regulations [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia) CLIA Regulations & Federal Register Documents (menu left column)

Personnel qualifications [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia) CLIA Regulations & Federal Register Documents (menu left column)

- ❑ Director – 493.1357 (duties 493.1359)
- ❑ Testing Personnel – 493.1363 (duties 493.1365)

**Oversight**

- ❑ Cost – \$200 every two years
- ❑ Surveys – no routine visits, complaints only

**\* Fecal leukocyte (WBCs)**

**Fern test**

**Potassium hydroxide (KOH)**

**Nasal smear for granulocytes**

**Pinworm**

**Post-coital (vaginal or cervical)**

**Semen analysis (presence / absence)**

**Urinalysis (microscopic) - including 2 or 3  
glass test**

**Wet mounts**

**Note: microscopic exams must be done by a state licensed MD, DO,  
dentist or mid-level practitioner**